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1 **Mechanical testing of internal fixation devices: A theoretical and practical**
2 **examination of current methods**
3

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Abstract

Successful healing of long bone fractures is dependent on the mechanical environment created within the fracture, which in turn is dependent on the fixation strategy. Recent literature reports have suggested that locked plating devices are too stiff to reliably promote healing. However, *in vitro* testing of these devices has been inconsistent in both method of constraint and reported outcomes, making comparisons between studies and the assessment of construct stiffness problematic. Each of the methods previously used in the literature were assessed for their effect on the bending of the sample and concordant stiffness. The choice of outcome measures used in *in vitro* fracture studies was also assessed. Mechanical testing was conducted on seven hole locked plated constructs in each method for comparison. Based on the assessment of each method the use of spherical bearings, ball joints or similar is suggested at both ends of the sample. The use of near and far cortex movement was found to be more comprehensive and more accurate than traditional centrally calculated interfragmentary movement values; stiffness was found to be highly susceptible to the accuracy of deformation measurements and constraint method, and should only be used as a within study comparison method. The reported stiffness values of locked plate constructs from *in vitro* mechanical testing is highly susceptible to testing constraints and output measures, with many standard techniques overestimating the stiffness of the construct. This raises the need for further investigation into the actual mechanical behaviour within the fracture gap of these devices.

Introduction

It is understood that the mechanical environment (the amplitude of movement occurring within the fracture) influences its healing. When a fixation system has been used to stabilise the fracture, this movement is dictated by the behaviour of the whole construct under the observed physiological loads. Claes et al. (1997) have suggested that for optimum healing the range of motion observed should be between 0.2-1.0 mm within a 3mm gap.

During the early phases of healing the behaviour of the bone – implant construct is primarily related to the physical characteristics of the fixator itself. The fixation type (plate, nail, external fixator), material (stainless steel, titanium), geometry (breadth, thickness and length), as well as the implanted configuration of screws and screw type; will all influence the deformation of the fracture under load. To determine the effect of each of these parameters on the mechanical environment, an appropriate set of loads and boundary conditions need to be defined that most closely reflect the observed mechanical environment *in vivo*. There is currently no standard test methodology which reflects this.

Previous mechanical testing has been conducted using a range of boundary conditions and loads, and using a variety of outputs for comparison (Table 1). Compression testing is commonly conducted on fracture fixation implants, as this is the primary mode of loading occurring physiologically. This compression is then converted into bending by the natural geometry of the bone.

Within the studies examining compressive loading of bone – implant constructs, the method of constraint of the sample varies considerably. Three methods of constraint are common, fixation of both translations and rotations at both ends of the sample (fully fixed), freeing the rotations at a single end of the sample while keeping the other fully fixed (fixed-free), and freeing rotations at both ends of the sample while keeping translations fixed (free-free). There has been no discussion

however, as to which of these methods of constraint is the most appropriate for compression testing of bone – implant constructs, or if any of them allow the natural bending behaviour of the bone.

Additionally, the reported outcome measures from these studies vary and again there is little discussion of the advantages or disadvantages of using each parameter. Stiffness is commonly reported and can be calculated globally using the applied load and the global deformation. Increasingly though the stiffness of constructs is calculated using the Interfragmentary motion or IFM. This parameter describes the motion occurring at the centre of the fracture gap under load. Alternatively, Bottlang et al. (2011; 2010) expand IFM into movements on the near and far cortex with respect to the fixation and Uhl et al. (2008) tracked changes in height of the fracture gap under load, placed at 90° and 160° from the fixation.

From this review of current practices, it is evident that a standardised testing methodology is currently lacking in terms of both sample constraints and measurement outputs. Therefore, the aim of this study was to characterise, from a mechanical engineering standpoint, the existing compression testing methodologies and to determine the most relevant output parameter. Discussion of engineering bending theory and constraint mechanisms will be coupled with an example of each method and output using a standardised single fracture fixation plate sample. A standard protocol for comparative testing of these devices will then be suggested.

Table 1 A sample of published literature on mechanical testing of fracture fixation systems

Authors	Year	Constraint	Deformation capture	Load (N)	Sample type	Geometry	Fixators	Fracture Gap (mm)
Duda et al.	1998	free-free	IFM	1377	Surrogate	cylinder	external fixator	4
Gaebler et al.	2001	free-free	global 1d	to failure	Surrogate	other	nail	55
Kassi et al.	2001	fully fixed	IFM	unspecified	Surrogate	cylinder	external fixator	unspecified
Duda et al.	2002	fully fixed?	IFM	500	Human	tibia	1 x 5 hole SS plate constructs	11
Stoffel et al.	2003	free-free	global 1d	200	Sawbones	cylinder	8 and 12 hole Ti plate constructs	6
Ahmad et al.	2007	fully fixed	global 3d	250	Sawbones	humerus	2x 7 hole SS plates	10
Epari et al.	2007	fully fixed	IFM	unspecified	Ovine	tibia	4 x external fixator, 2 x nail	3
Meleddu et al.	2007	fixed-free	IFM	unspecified	Surrogate	cylinder	external fixator	unspecified
Augat et al.	2008	fixed-free	global 3d	100	Human	tibia	nail	8
Snow et al.	2008	fully fixed	global 1d	450	Synbone	cylinder	2x 8 hole SS plate constructs	10
Uhl et al.	2008	fixed-free	90 and 160deg	355	PU	cylinder	3 x SS plate constructs	2
Bottlang et al.	2009	fixed-free	Near and Far cortex	1000	Sawbones	cylinder	2 x 11 hole Ti plate constructs	10
Fitzpatrick et al.	2009	fixed-free	IFM	1000	Surrogate	cylinder	4 x SS plate constructs	10
Gardner et al.	2009	fixed-free	global 1d	200	Sawbones	cylinder	2 x 11 hole SS plate constructs	18
Penzkofer et al.	2009	fixed-free	IFM	100	Human	tibia	nail	8
Bottlang et al.	2010	fixed-free	Near and Far cortex	400	Sawbones	cylinder	3 x 11 hole Ti plate constructs	10
Gardner et al.	2010	unspecified	global 1d	700	Surrogate	cylinder	2 x 10 hole SS plate constructs	10

Methods Theory

Boundary Conditions

The three reported methods of constraint during compression testing were first assessed from an engineering perspective to determine their effect on the bending mode of the samples. As an initial simplification, the bone was assumed to be a solid without any fixation, in which case the effect of the three load cases on the deformation mode of the sample can be related to the bending modes of intact beams with the same end constraints (Figure 1).

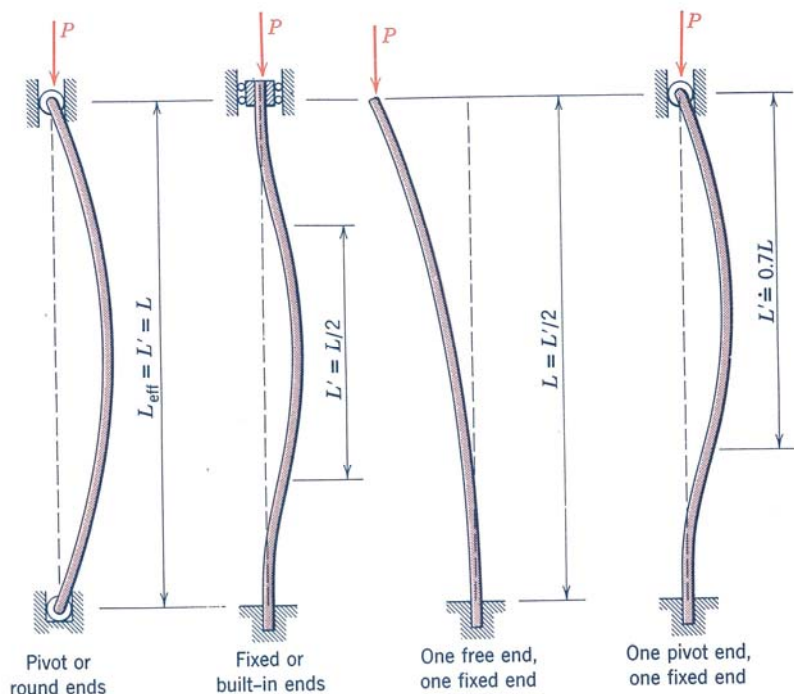


Figure 1: The effect of end constraints on the effective length of simple beams under load. Adapted from Riley et al. (1995)

In the figure, the effect of the various end constraints on the effective length (L) of the beams can be seen. The only constraint system in which the effective length is equal to the true length is the case of two pivot or round ends allowing free rotation at each end. The other two common compression cases: fixed-fixed and fixed-free both result in a dramatic shortening of the effective length of the column to $0.5L$ and $0.7L$ respectively. Conversely, allowing free rotations and translations at one end results in a doubling of the effective length.

While the constructs of interest in this paper are more complex than simple beams, with both discontinuities (fractures or osteotomies), and additional high stiffness members applied off axis (fixators) the way in which they will bend under a compressive load will follow the same basic pattern as for these simple beams.

Outputs

The mechanical testing of bone - implant constructs lends itself to a range of different output parameters. The global stiffness or the response of the entire system to load is a commonly reported parameter as it allows simple comparison between constructs based on a single number. This value is typically calculated from the load vs. deformation behaviour as recorded by the mechanical testing machine. However, there are a number of issues with the usage of this parameter, it is highly dependent on the constraints on the system, making samples *within* a study comparable but diminishing its use across studies.

Another increasingly common output measure is the movement within the fracture gap, but even within this one parameter there are differences in definition and reporting. The initial definition of interfragmentary motion, IFM, was as the movement at the centre of the fracture gap, calculated as the difference in the new position of this point as seen by the upper and lower segments under load (Duda et al., 1998). This was then coupled with the calculation of the relative rotations of the fragments from attached optical marker rigid bodies. While the definition of this seems reasonable the calculation generates a number of problems.

Examining the translational aspects, calculation only at the centre of the fracture gap, results in reporting the median deformation and not the full range experienced. The limited scope of this result is shown schematically in Figure 2 for the case of looking at the vertical translations only. Three hypothetical cases of deformation within the fracture gap are shown (A, B and C), in each case the original location of the bones are outlined in black and the resultant deformed locations shown

114 outlined in red. The centre of the fracture gap about which the IFM is calculated is indicated by a
 115 star. In each case the deformation is highlighted in grey, the sum of the deformation of the upper
 116 and lower fragments is then shown in the cumulative deformation plots at the bottom of the figure.
 117 The location of the centre of the fracture gap (star) is shown for reference. Case A and B, both result
 118 in the same value of IFM (dotted red line in the cumulative deformation plots), and yet their near
 119 and far cortex deformations are very different. Case C, shows the case of zero IFM, with large near
 120 and far cortex movements (though small movements are equally possible). This case reflects simply
 121 that the instantaneous centre of rotation of the two fracture surfaces happens to be at the location
 122 about which the IFM is calculated. In each case, the reported central IFM value is correct, but does
 123 not depict the complete story of the deformation.

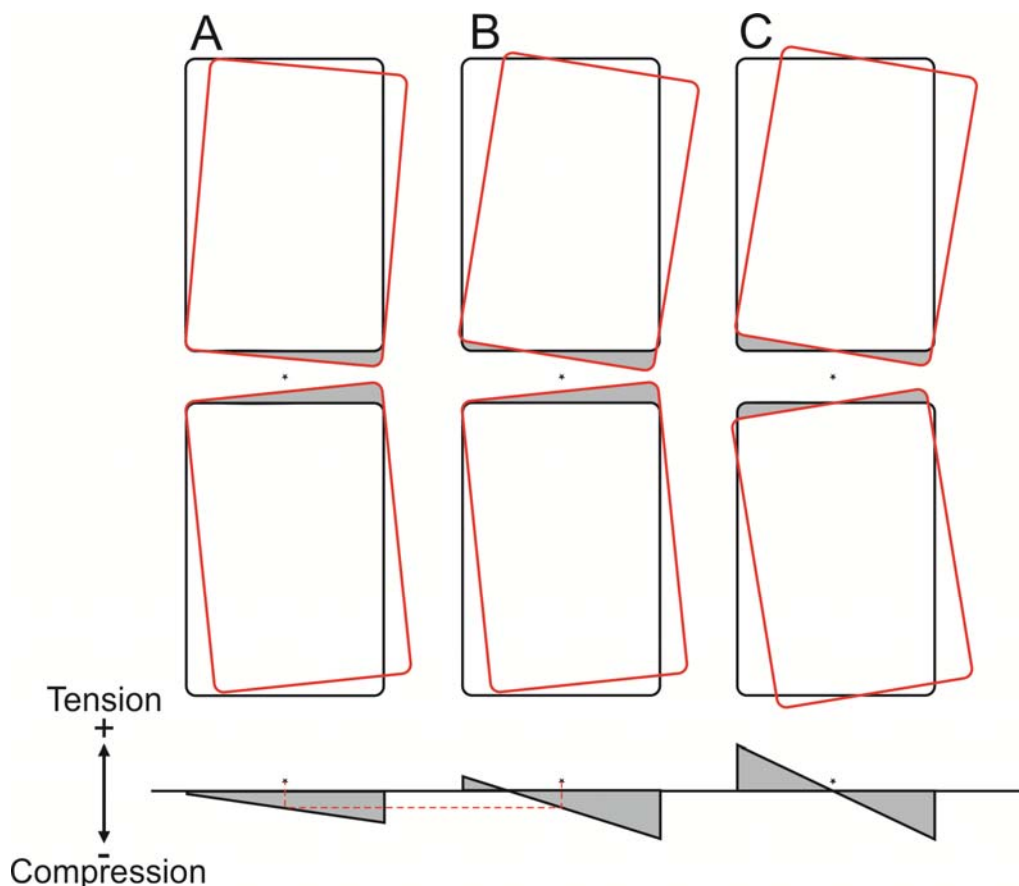


Figure 2 Three hypothetical cases of deformation within the fracture gap, in each case the original location of the bones are outlined in black and the resultant deformed locations shown outlined in red. The centre of the fracture gap about which the IFM is calculated is indicated by a star. In each case the deformation is highlighted in grey, the sum of the deformation of the upper and lower fragments is then shown in the cumulative deformation plots at the bottom of the figure. The location of the centre of the fracture gap (star) is shown for reference.

The issues highlighted above in using a central point for reporting of IFM are somewhat mitigated by reporting the movements on opposing bone cortices. With internal fixation strategies such as plates, this is often reported in terms of the two cortices of primary interest, being the 'near' and 'far' cortex with respect to the plate positioning. Reporting of these two positions greatly enhances the descriptiveness of the data. In terms of translations, it also allows the deformation to be measured directly using mechanical means such as LVDT's or dial gauge displacement sensors, though this is often limited to a single direction of movement.

Calculation of relative rotations of the bone fragments poses another problem. In the original optical tracking method the optical markers themselves are used to form a local coordinate system and it is the rotation of this local coordinate system that is tracked, not the rotation of the actual bone. It is important to note that rotations are always relevant to their local coordinate system (i.e. the orientation of the marker frames) and not the global coordinate system (the orientation of the bone/test rig). This presents a problem as the markers are mounted remotely to the fracture gap and their orientation is not assured. This discrepancy is of particular concern when testing torsion or bending modes, in which rotations are high. To reduce the magnitude of this error the method proposed below uses imaginary points located on the fracture surface to calculate the rotations of the fragments directly, in a coordinate system directly relevant to the bone and fixation orientation.

Methods Mechanical Testing

From the theoretical assessment of the effect of constraint on bending length, it was determined that using free-free end conditions was likely to result in bending across the full length of the sample, while fixing the rotations at either or both ends would act to artificially shorten the sample and increase the apparent stiffness. However, as bone-implant constructs are considerably more complex, the effect of each of the constraint modes was tested mechanically with a single plated construct as an example of each theoretical approach.

To remove any effects of differing geometry and material properties a cylindrical bone analogue was used (Sawbones 4th generation (Pacific Research Laboratories, USA), 250mm long, 20mm OD Cylinder, 3mm wall) with a seven hole, stainless steel, 4.5mm locking compression plate (LCP, Synthes, Switzerland). The plate was positioned 2mm from the analogue surface and six locking screws were positioned in the three most proximal and distal holes, leaving a working length of one empty hole centrally located above a 3mm osteotomy. The ends of the sample were then potted in stainless steel cups using Paladur dental acrylic (HeraeusKulzer GmbH, Germany).

Optical tracking of the movement of the upper and lower halves of the construct was conducted throughout all testing using an Optotrak Certus system (Northern Digital Inc., Canada). Two rigid bodies, each with three infrared optical markers were attached to each construct, above and below the osteotomy. After positioning a sample within one of the test rigs the initial location of the fracture gap was digitised relative to these markers (Figure 3). The location of each rigid body was then tracked throughout testing at a rate of 100Hz.

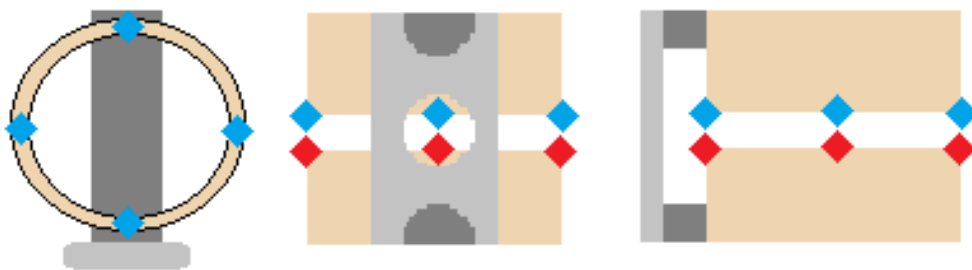


Figure 3 Schematic of the eight digitised cortex points. With four on each of the upper and lower surface located on the near and far cortex and at the maximum and minimum in the alternate plane.

The sample was tested in three test rigs: fully fixed, in which the mounting cups were directly attached to the base plate of the testing machine and the load cell; fixed – free, in which a test rig using a ball joint to connect to the load cell was used; and free – free, in which a spherical bearing attachment was used at both ends of the sample (Figure 4).

Using an Instron Biaxial testing machine (8874, Instron Pty Ltd, USA) five cycles of compressive loading to 200N were applied to the samples at 0.05Hz, while maintaining zero rotation. At the fifth loading peak the sample was held in place (position controlled) for a period of 5 seconds for optical data capture.

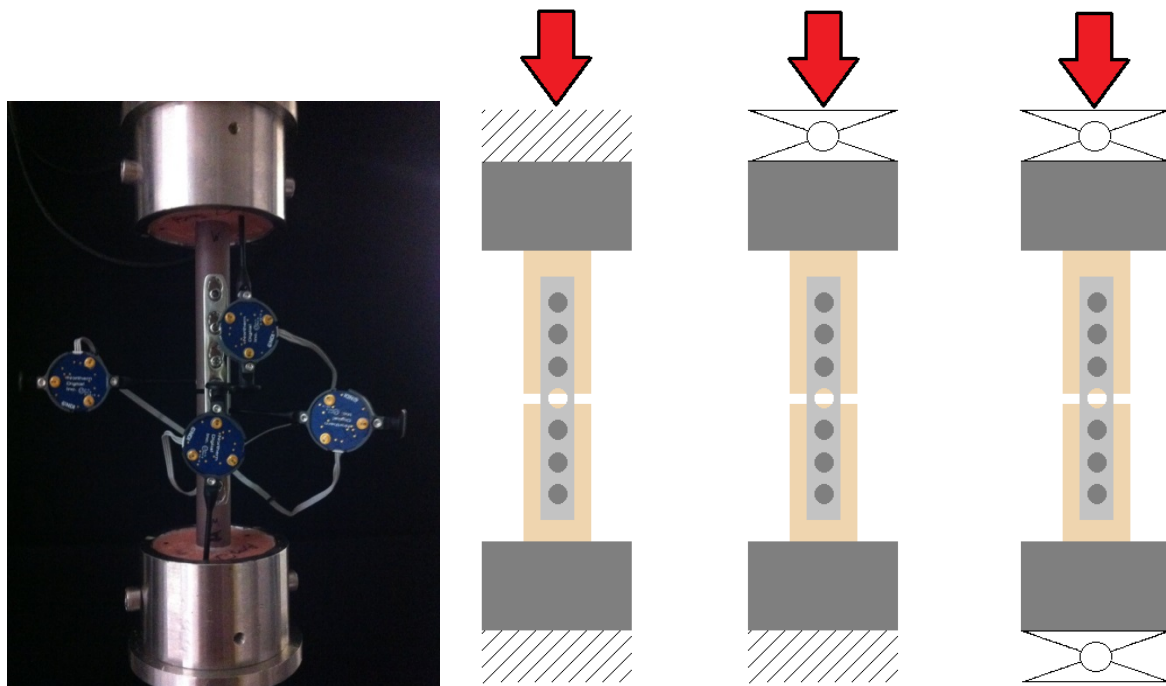


Figure 4 A photograph of the fully fixed test setup, with Optotrak rigid bodies attached, with a schematic of the three test rig constraints, on the left fully fixed (all translations and rotations fixed); in the centre fixed-free (all translations and rotations fixed at the base, free rotation but fixed translation at the top) and Fully Free (free rotations top and bottom, fixed translations top and bottom) on the right.

Using the captured optical data, the position of points on the upper and lower surface of the fracture gap, on the near cortex (immediately under the plate), and the far cortex (Opposite side of the plate) were calculated using vector mathematics. The difference between the upper and lower surfaces under load is also reported.

Results

The closure of the fracture gap on the near and far cortex under 200N of load is reported in Table 2 for each of the experimental setups. From this result, the effect that the constraint mechanism has on the deformation is evident. Both fixed methodologies result in dramatically reduced

deformations and hence over estimation of the stiffness of the construct. This pattern is in keeping with the theoretically proposed effect on the bending behaviour of the samples.

Table 2: Deformation at the near and far cortex; and IFM, of the plated bone analogues in each of the test scenarios. Fully fixed with both ends constrained, Fixed-Free with one end fully fixed and the other free to rotate, and Free-Free in which both ends are free to rotate. A negative number indicates the closing of the fracture gap.

	Fully Fixed	Fixed-Free	Free-Free
Near Cortex	-0.02mm	-0.07mm	-0.14mm
Far Cortex	-0.11mm	-0.21mm	-0.57mm
IFM	-0.07mm	-0.14mm	-0.35mm
Difference IFM to cortex movements	$\pm 0.04\text{mm}$	$\pm 0.07\text{mm}$	$\pm 0.21\text{mm}$

The centrally located IFM is also reported in Table 2 for reference. As the average deformation across the gap, the difference between its calculated values and the corresponding near and far cortex movements increase as the deformation range increases. For completeness, were the reporting of IFM to be preferred the \pm range should also be added onto the reported values giving IFM of: Fully-Fixed $-0.07 \pm 0.04\text{mm}$, Fixed-Free $-0.14 \pm 0.07\text{mm}$ and Free-Free $-0.35 \pm 0.22\text{mm}$.

The stiffness of fracture fixation constructs is commonly reported. This is typically calculated from the load-deformation behaviour recorded by the testing machine. The effect that the method of constraint has on the deformation and hence stiffness, is apparent (Table 3). In each case the plated construct was identical and so its stiffness had not changed. Instead the imposed stiffness of the constraint method is reflected in the calculated value.

Table 3: Stiffness of the plated bone analogues in each of the test scenarios as calculated from the Instron load – deformation data (linear regression on the final cycle, R2=0.999). Fully fixed with both ends constrained, Fixed-Free with one end fully fixed and the other free to rotate, and Free-Free in which both ends are free to rotate.

Stiffness	Fully Fixed	Fixed-Free	Free-Free
	(N/mm)	(N/mm)	(N/mm)
Instron	2500	662	215
Near Cortex	10000	2857	1428
Far Cortex	1818	952	351
IFM	2857	1428	571

Discussion

For the mechanical testing of fracture fixation plates, three methods of constraint were found to have been used in the literature. These constraints were assessed from a theoretical point of view and it was determined that using fixed end constraints would likely have a large influence on the deformation behaviour of the sample resulting in over estimation of construct stiffness – the primary parameter often used to critique these devices. As the bone-plate constructs are more complicated than the simple beam theory applied to assess the constraint mechanisms it was determined to conduct mechanical testing on a single plate – bone analogue construct. The results from this construct show a similar pattern in deformation to that predicted by the theoretical analysis. The original assessment that using fixed end conditions over constrains the sample and prevents natural deformation through bending, was found to be true.

Additional to the assessment of constraint mechanism, the reported output parameters commonly used in the literature were also assessed. Again a theoretic analysis of the options was conducted and the preferred methodology determined to be the calculation or measurement of deformations on both the near and far cortex (with respect to the plate). This method was used to assess the differences in deformations across the fracture gap with each of the different constraint

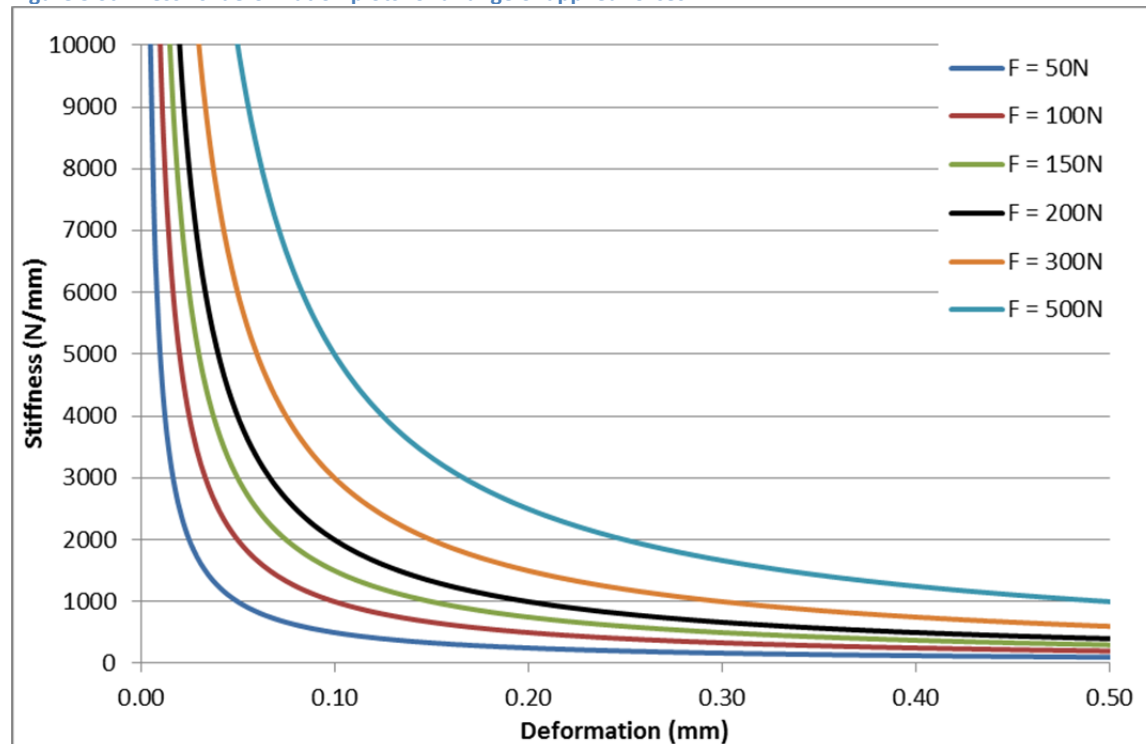
mechanisms. For comparison the commonly used IFM was also calculated and reported along with the \pm range that would need to be associated with it to fully represent the deformation in the fracture gap.

The stiffness of the constructs calculated using the testing machine, as well as the IFM and cortex movements were also reported. Dramatic differences in the calculated value are seen. Yet there is no difference in the structure of the sample, only in its constraint mechanism and measurement point. While the calculated stiffness values vary by thousands of N/mm and therefore seem significant, the corresponding deformations vary by only tenths of a millimetre and therefore seem insignificant. This dichotomy is brought about by the mathematical relationship between stiffness and deformation, Hooke's law.

Hooke's law is traditionally expressed as $F = kx$, where F is the force, k the stiffness and x the deformation. To calculate stiffness from mechanical testing data this is rearranged to $k = F/x$ or $k = F \cdot (1/x)$. For a constant force the stiffness therefore has a $1/x$ relationship to deformation. This is expressed graphically in Figure 5 for a range of forces.

From this plot it can be seen that small deformations result in very high stiffness values. The error of the measurement technique then becomes critically important if stiffness is to be reported as does the stiffness of the constraint method. As the stiffness of the constraint decreases, the deformation achieved increases, shifting the result to the right of the plot into the flatter region where deformation accuracy is less critical. Highly stiff test constraints however, minimise deformation, and maximise the effects of measurement accuracy. For example in the fully-fixed constraint a deformation accuracy level of $\pm 0.01\text{mm}$ from the Instron results in a stiffness range of 2222 to 2857 N/mm. The effect is exacerbated further to achieve a stiffness range of 6667 to 20 000 N/mm, when calculating using the Optotrak data at the near cortex.

Figure 5 Stiffness vs. deformation plots for a range of applied forces.



Looking back at the fixation studies described in Table 1, we can now make a number of comments about the validity of their results in absolute terms. It should be noted that most of these studies are comparative in nature (one construct vs another) so the general patterns reported are likely still valid, but their contribution to the overall understanding of fixation systems may be questionable. From this work it is clear that those studies utilising fully fixed boundary constraints, or even fixed-free systems are dramatically over estimating the stiffness of the constructs they are reporting on. Under reporting of deformation – using global outcomes or IFM, is very common, this potentially has a greater effect on reported outcomes than the constraint method. Reporting stiffness from low accuracy global deformation readings leads to apparently large differences being reported between constructs, when perhaps there is no meaningful clinical difference between their deformation patterns. Caution should be used when interpreting previous literature, and care taken to understand the effects of the mechanical testing choices that were made.

Limitations

This study was intended as an exploration of the application of mechanical engineering theory to the testing of orthopaedic bone fracture fixation constructs. As such the focus is on a single sample as an example of the theory, rather than a thorough investigation of the mechanical behaviour of this specific construct. The inclusion of further samples may change the specific stiffness and deformation values obtained, however the patterns will remain the same. In order to investigate the effect of constraint mechanisms and deformation outputs, all other variables were selected to be as consistent and controlled as possible, and held static throughout the tests. For this reason a bone substitute material was used in the form of a Sawbones cylinder, this removes the complexities of both geometry and material properties inherent in natural bone. This will however have an impact on the specific behaviour of the bone-plate construct under investigation, so reported values should be used with caution.

Conclusion

Examination of three methods of sample constraint demonstrated the effect of mechanical testing apparatus selection on the apparent stiffness of fixation constructs. With decreasing deformation associated with increases in apparent stiffness, the effect of measurement accuracy and deformation measurement location become major contributors to the reported stiffness values. Differences between the effect of reporting IFM and cortex points was also demonstrated. To increase comparability between studies, mechanical testing methodology and outputs need to be standardised. It is therefore suggested that test rigs utilising two ball joints or spherical bearings are used and that deformations on the near and far side of the fracture gap are reported.

Conflict of interest statement

The authors are not aware of any conflict of interest, financial or otherwise which could influence this work.

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